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Sy:\_\_\_\_\_Sarah M. Barn

Customer Number: 22,852

Attorney Docket No. 06843.0067-02000

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Aya JAKOBOVITS et al.

Application No.: 09/187,693

Filed: November 5, 1998

For: HUMAN MONOCLONAL

Confirmation No. 3392

Broup Art Unit: 1644

Examiner: Phuong N. HUYNH

Description No. 3392

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Description No. 3392

Des

HUMAN MONOCLONAL
ANTIBODIES TO EPIDERMAL

GROWTH FACTOR

**RECEPTOR** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 MAIL STOP RCE

Sir:

## **INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO 1449. This Information Disclosure Statement (Statement) is being filed, to the undersigned's knowledge, before the mailing date of a first Office Action on the merits after the Request for Continued Examination (RCE) was filed in this case.

Nine of the documents listed on the attached Form PTO 1449 were cited in a communication in a counterpart Patent Cooperation Treaty application. Copies of those documents are enclosed. A copy of that communication is also enclosed.

Application No.: 09/187,693 Attorney Docket No. 06843.0067-02000

Copies of the remaining documents listed on the attached Form PTO 1449 were previously submitted or were cited by the Examiner in:

U.S. Patent Application No. 09/162,280, filed September 28, 1998; and/or

U.S. Patent Application No. 08/851,362, filed May 5, 1997, now U.S. Patent No. 6,235,883;

both of which Applicants rely upon for the benefits provided in 35 U.S.C. § 120.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the claimed invention over the listed documents should one or more of the documents be applied against the claims of the present application.

Application No.: 09/187,693 Attorney Docket No. 06843.0067-02000

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 8, 2004

Jennifer L. Elliot

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By:

Seath M. Boxon.

APR 0 8 2004 8

OMB No. 0651-0011

## INFORMATION DISCLOSURE CITATION

| Atty. Docket No. 06843.0067-02000 |                       | Appln. No. 09/187,693 |
|-----------------------------------|-----------------------|-----------------------|
| Applicant                         | Aya JAKOBOVITS et al. | Conf. No. 3392        |
| Filing Date                       | November 5, 1998      | Group: 1644           |

|                      |                    | U.S. PATENT | DOCUMENTS |       |              |                            |
|----------------------|--------------------|-------------|-----------|-------|--------------|----------------------------|
| Examiner<br>Initial* | Document<br>Number | Issue Date  | Name      | Class | Sub<br>Class | Filing Date If Appropriate |
|                      |                    |             |           |       |              |                            |

| FOREIGN PATENT DOCUMENTS |                    |                     |         |       |              |                          |
|--------------------------|--------------------|---------------------|---------|-------|--------------|--------------------------|
|                          | Document<br>Number | Publication<br>Date | Country | Class | Sub<br>Class | Translation<br>Yes or No |
|                          | 712 863 A1         | May 22, 1996        | EPO     |       |              |                          |
|                          | 586 002 A2         | Aug 18, 1993        | EPO     |       |              |                          |
|                          | WO 96/34096 A      | Oct 31, 1996        | PCT     |       |              |                          |
|                          | WO 96/40210 A      | Dec 19, 1996        | PCT     |       |              |                          |
|                          | WO 98/24893 A      | Jun 11, 1998        | PCT     |       |              |                          |
|                          |                    |                     |         |       |              |                          |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |  |  |  |  |  |
|--|--|--|--|--|--|
|  | J. Corvalan et al., January 1, 1997, "Generation of fully human high affinity monoclonal antibodies to EGF receptor in mice," The Journal of Allergy and Clinical Immunology, 99(1, part 2, supp.): s15.       |  |  |  |  |
|  | GenBank Accession Number Z70619, <i>H. sapiens</i> mRNA for immunoglobulin heavy chain variable regions (6D4-A5, VH4, 4-31/DP-65), accessed December 3, 1998 (1996).   |  |  |  |  |
|  | GenBank Accession Number Z70658, <i>H. sapiens</i> mRNA for immunoglobulin heavy cahin variable regions (83-6H3, VH4, 4-61/DP-66), accessed December 3, 1998 (1996).   |  |  |  |  |
|  | A. Jakobovits et al., January, 1997, "Humoral immunity in mice engineered with megabase human heavy and kappa light chain YACs," The Journal of Allergy and Clinical Immunology, 99(1, part 2, supp.): s113.   |  |  |  |  |
|  | A. Jakobovits et al., April 6, 1998, "Production and selection of antigen-specific fully human monoclonal antibodies from mice engineered with human Ig loci," Advanced Drug Delivery Reviews, 31(1-2): 33-42. |  |  |  |  |
|  | A. Jakobovits, April 1998, "The long-awaited magic bullets: therapeutic human monoclonal antibodies from transgenic mice," Expert Opinion on Investigational Drugs, 7(4): 607-614.                             |  |  |  |  |
|  | J. Klein, 1982, Immunology: The Science of Self-Nonself Discrimination, John Wiley & Sons: New York, NY p. 176-183.  |  |  |  |  |

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April 8, 2004

Sarah M. Barnett

# INFORMATION DISCLOSURE CITATION

OMB No. 0651-0011

| Atty. Docket Not 171496845 0067-02000 |                       | Appln. No. 09/187,693 |
|---------------------------------------|-----------------------|-----------------------|
| Applicant                             | Aya JAKOBOVITS et al. | Conf. No. 3392        |
| Filing Date                           | November 5, 1998      | Group: 1644           |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)   |  |  |  |  |
|--|--|--|--|--|
| T. Matsumoto et al., March 1997, "Chimeric monoclonal antibody (Mab) C225 to the epidermal growth factor receptor (EGF-R) inhibits the growth of human transitional cell carcinoma (TCC) in the bladder of nude mice," Proceedings of the American Association for Cancer Research, 38: 229. |  |  |  |  |
| M. Mendez et al., February 1997, "Functional transplant of megabase human immunoglobulin loci recapitulates human antibody response in mice," Nature Genetics, 15: 146-156.  |  |  |  |  |
| H. Modjtahedi et al., 1994, "The receptor for EGF and its ligands: expression, prognostic value and target for therapy in cancer (Review)," International Journal of Oncology 4:277-296.   |  |  |  |  |
| G. Schulz et al., 1979, Principles of Protein Structure, Springer-Verlag: New York, NY, pp. 14-16.   |  |  |  |  |
| International Search Report for PCT Application No. PCT/US98/09160.  |  |  |  |  |

| *Examiner: Initial if reference consider through citation if not in communication to application. |  | Date Considered  |
|---|--|--|
|   |  | onsidered, whether or not citation is in conformance with MPEP 609; draw line of in conformance and not considered. Include copy of this form with next applicant. |
| Form PTO 1449   |  | Patent and Trademark Office - U.S. Department of Commerce  |